Reference value of transcutaneous oxygen measurement in diabetic patients compared with nondiabetic patients

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Purpose: **This study evaluated the values of transcutaneous oxygen tension ($TcPo_2$) measurement in diabetic patients compared with nondiabetic patients and assessed its reproducibility.**

Methods: **In 60 diabetic patients (type 1 and type 2 diabetes mellitus) without signs of peripheral arterial disease or neuropathy, we measured $TcPo_2$ at the chest and foot and compared these measurements with 60 age- and sex-matched nondiabetic patients in a cross-sectional fashion. The reproducibility of $TcPo_2$ in terms of interobserver variability was also assessed.**

Results: **Diabetic patients had a mean ± SD $TcPo_2$ value at the foot of 50.02 ± 8.92 mm Hg, which was significantly lower compared with 56.04 ± 8.80 mm Hg in nondiabetic patients ($P < .001$). At the chest wall, values for $TcPo_2$ were 51.77 ± 11.15 mm Hg, and 58.22 ± 12.47 mm Hg for diabetic patients and nondiabetic patients, respectively ($P = .003$). Regression analysis showed that $TcPo_2$was significantly associated with diabetes mellitus (coefficient = −0.258; $P = .004$), and with having a first-degree relative with diabetes mellitus (coefficient = −0.265; $P = .003$). Furthermore, the interobserver variability showed a substantial correlation for both measurements at the chest ($P < .001$; $r = 0.654$; intraclass correlation coefficient [ICC] = 0.79) and at the dorsum of the foot ($P < .001$; $r = 0.426$; ICC = 0.60).**

Conclusion: **Diabetic patients without signs of peripheral disease or neuropathy had significantly lower $TcPo_2$ values compared with age- and sex-matched nondiabetic patients. The influence of the examiner on the variance in $TcPo_2$ measurements was relatively small. We advocate the use of $TcPo_2$ measurement in diabetic patients to detect subclinical microvascular impairment as an additional tool to assess peripheral vascular disease. (J Vasc Surg 2008;48:382-8.)**

Transcutaneous oxygen tension ($TcPo_2$) measurement is a noninvasive diagnostic study that provides information about the supply and delivery of oxygen to the underlying microvascular circulation by recording the partial pressure of oxygen at the skin surface. The amount of oxygen detected by the sensor is a balance of oxygen delivery and local physiologic demands and reflects the metabolic status of the skin.[1] The $TcPo_2$ measurement is used in determining amputation level,[2,3] wound healing evaluation,[4] hyperbaric therapy,[5] and peripheral arterial disease assessment,[6,7] including the status of spinal cord stimulation[8] and revascularization procedures.[3,9,10]

In the literature, a commonly accepted reference value with $TcPo_2$measurement for the diagnosis of peripheral arterial disease is approximately 60 mm Hg, regardless of electrode location.[7,11,12] For wound healing to occur, studies found that the $TcPo_2$ should be >40 mm Hg, and impaired wound healing is noted with values between 20 and 40 mm Hg. Failure of wound healing is demonstrated with $TcPo_2$values of <20 mm Hg.[13,14]

The most appropriate clinical role for $TcPo_2$ measurement is to assist in the assessment of severe ischemia. Because the measurements are not affected by arterial calcification, it is particularly useful in evaluating diabetic vascular disease. For diabetic patients, however, $TcPo_2$ values might not be the same as for nondiabetic patients because potential subclinical microangiopathy may cause alterations in capillary flow. The use of the $TcPo_2$measurement in the diabetic population has been studied previously,[4,15,16] but consistent reference values for diabetic patients without signs of peripheral arterial disease or neuropathy are lacking. With the increasing prevalence of obesity, the metabolic syndrome, and associated diabetes mellitus (diabetes), and previous studies reporting that tissue oxygenation measured by $TcPo_2$ in patients with diabetes is impaired,[17,18] determining a reference value for $TcPo_2$ in the diabetic population could be of help in clinical daily practice.

This study evaluated the reference value for $TcPo_2$ measurement in diabetic patients compared with nondiabetic patients and secondarily assessed the reproducibility of $TcPo_2$in terms of interobserver variability.

METHODS

Study design and patients. We performed a cross-sectional study at the Ikazia Hospital Rotterdam, The Netherlands, a large community hospital with a specialized

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Competition of interest: none.

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surgical laboratory experienced in the field of vascular diseases. The study included 60 diabetic patients (types 1 or 2) from our outpatient clinic with diagnosed diabetes for at least 1 year and without signs of peripheral arterial disease and neuropathy. Selection criteria were on the basis of the medical history, a comprehensive interview, and levels of fasting blood glucose and glycosylated hemoglobin (HbA_{1C}). Also invited to participate in the study were 60 nondiabetic patients to match for age and sex.

A physical examination including palpation of the pedal pulses, vibration thresholds, and standard fiber testing was used to exclude peripheral arterial disease, injury to the extremities, peripheral neuropathy and spinal conditions, cardiovascular disease, pulmonary disease, and psychiatric illness. Further evaluation of study participants considered age, sex, height, weight, body mass index (BMI), smoking habits, family history of diabetes, and if appropriate, type of diabetes, type of medication, and diabetes duration.

The study was approved by the local ethics committee, and was performed according to the declaration of Helsinki.[19] In accordance with institutional guidelines, written informed consent to be part of this study and for their study data to be reported in the literature for the purpose of scientific articles was obtained from all patients before their participation.

Measurement of $TcPo_2$. A Radiometer TCM400 (Copenhagen, Denmark) $TcPo_2$ monitor was used to simultaneously measure the $TcPo_2$ values at the chest and at the dorsum of the foot. The laboratory room temperature was maintained at approximately 25°C. All patients acclimatized for a minimum of 10 minutes before commencing the study, during which the device was calibrated at 159 mm Hg according to the manufacturer's guidelines.[20] The measurements were simultaneously performed on one randomly chosen lower extremity by two different vascular technologists with the patient resting in supine position during one session, each applying one electrode at the dorsum of the foot and one reference at the thorax. The reported values represent averages of the measurements assessed by both observers.

At the measured site, skin was shaved and cleaned with alcohol. A self-adhesive ring was filled with a buffered solution, both supplied by the manufacturer, and the electrode, heated to a temperature of 43°C, was attached. The electrode at the dorsum of the foot was placed between the first and second metatarsal heads just proximal to the first and second toe, not over a visible vein, bony, or tendon structure. The electrode at the chest was placed by the same observer on the ipsilateral anterior chest wall at the midclavicular line and infraclavicular fossa. The $TcPo_2$ value was recorded for analysis after obtaining a stable reading after 20 minutes. Three registered vascular technologists were involved, all experienced in $TcPo_2$ measurement.

Statistical analysis. All continuous variables were expressed as means ± standard deviation (SD). Significance of differences between the group means was assessed by using the Student *t* test, or if nonparametric, by using the Mann-Whitney *U* test. Significant differences between nominal and categoric variables were assessed by using Fisher's exact test. A one-way sensitivity analysis was performed to test whether $TcPo_2$ measurements >80 mm Hg had influenced the results. A subgroup analysis stratifying for type 1 and type 2 diabetes was performed within the group of diabetic patients. We then compared the subgroups of type 1 and type 2 diabetic patients separately with the group of nondiabetic patients. Backward multiple linear regression analysis was used to determine which factors were significantly associated with $TcPo_2$.

Data from both observers were plotted using Bland-Altman graphs enabling an appreciation of the distribution of error.[21] Typical error was calculated using the SD of the differences.[22] The interobserver variability was assessed by using the Pearson correlation coefficient. However, because our data include more than one observation on each individual and outliers were present, the intraclass correlation coefficient (ICC) was calculated as well, using a two-way mixed-effects model with absolute agreement definition. The ICC is defined as the proportion of variance of an observation due to between-subject variability in the true scores and can be interpreted as poor (ICC <0.20), fair (0.20 to 0.40), moderate (>0.40 to 0.60), substantial (>0.60 to 0.80), and almost perfect (>0.80 to 1.00).[23,24]

Significance was determined at a two-sided $P < .05$ and expressed with the 95% confidence interval (CI). All data were collected in an Excel database (Microsoft Inc, Bellingham, Wash). The analysis was performed using SPSS 12.1 software (SPSS Inc, Chicago, Ill).

RESULTS

The study included 60 diabetic patients and 60 nondiabetic patients matched for age and sex. Demographics and clinical characteristics of this study population are reported in Table I. Smoking habits, defined as current or never/ever (>1 year) were equally distributed among diabetic patients and nondiabetic patients (13 of 60 vs 10 of 60; $P = .643$; Table I). Significantly more diabetic patients had a first-degree relative who was diagnosed with diabetes (36 vs 21; $P = .010$) but had a lower BMI (27.20 ± 5.73 vs 30.21 ± 6.25 kg/m^2; $t = 2.74_{118}$, $P = .007$) compared with the nondiabetic patients (Table I). Within the diabetic patients, however, positive family history of diabetes (13 of 25 vs 23 of 35; $P = .293$) and BMI ($t = 2.14_{58}$ $P = .487$) were equally distributed between type 1 and type 2 diabetic patients (26.59 ± 3.77 and 27.64 ± 6.81 kg/m^2, respectively).

Fig 1 illustrates the mean values and corresponding 95% CI for $TcPo_2$ for diabetic and nondiabetic patients: The averaged mean values for $TcPo_2$ measurements (mm Hg) were, respectively, 50.02 ± 8.92 and 56.04 ± 8.80 at the dorsum of the foot and 51.77 ± 11.15 and 58.22 ± 12.47 at the chest wall. When diabetic and nondiabetic patients were compared, the absolute difference of $TcPo_2$ values measured at the foot and chest were 6.02 mm Hg (95% CI, 2.81-9.22; $P < .001$) and 6.45 mm Hg (95% CI, 2.17-10.73; $P = .003$), respectively. The absolute differences for $TcPo_2$ values between type 1 and type 2 diabetics measured at

Table 1. Comparison of demographics and clinical characteristics of diabetic patients and nondiabetic patients

Demographic	*Diabetic patients*	*Nondiabetic patients*	P
Patients, No.	60	60	
Type of diabetes, No.			
Type 1	25	NA	NA
Type 2	35	NA	NA
Age, mean ± SD, y			
Overall	58.1 ± 14.9	57.2 ± 14.7	.756[a]
Type 1	48.7 ± 15.1	NA	NA
Type 2	64.8 ± 10.5	NA	NA
Age at diabetes diagnosis, y			
Type 1	27.1 ± 15.3	NA	NA
Type 2	56.0 ± 10.4	NA	NA
Sex, No. (%)			
Male	24 (40)	24 (40)	1.000[b]
Female	36 (60)	36 (60)	
Smoking habit, No. (%)			
Yes	13 (22)	10 (17)	.643[b]
No/former	47 (78)	50 (83)	
Family history of diabetes, No. (%)[c]			
Yes	36 (60)	21 (35)	.010[b]
No	24 (40)	39 (65)	
BMI, mean ± SD kg/m^2	27.2 ± 5.73	30.2 ± 6.25	.007[a]
Fasting blood glucose, mean ± SD mmol/L	8.9 ± 2.9	5.4 ± 0.9	<.001[d]
HbA_{1c}, %	7.7 ± 1.3	NA	NA

BMI, Body mass index; *NA,* not applicable; *SD,* standard deviation.
[a]Student's *t* test.
[b]Fisher's exact test.
[c]Family history of diabetes mellitus in a first-degree relative.
[d]Mann-Whitney *U* test.

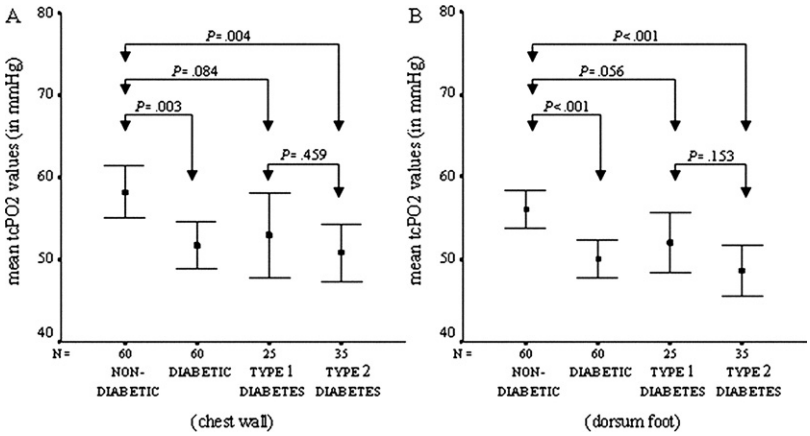

Fig 1. Mean values and corresponding 95% confidence intervals are shown for transcutaneous oxygen tension *($TcPO_2$)* measured in mm Hg at the **(A)** chest wall and **(B)** dorsum of the foot for diabetic patients and nondiabetic patients.

foot and chest were 3.35 mm Hg (95% CI, –1.28 to 7.99; P = .153), and 2.18 mm Hg (95% CI, –3.68 to 8.05; P = .459) and showed no significant difference.

After comparing nondiabetic patients with type 2 diabetic patients, however, both the values for $TcPo_2$ measured at the dorsum of the foot and chest wall were significantly different, with absolute differences of 7.41 mm Hg (95% CI, 3.68–11.15; P < .001), and 7.36 mm Hg (95% CI, 2.41–12.31; P = .004), respectively. The absolute differences for $TcPo_2$ between nondiabetic patients and those with type 1 diabetes were 5.18 mm Hg (95% CI, –0.72 to 11.07; P = .084) for $TcPo_2$ values measured at the chest and 4.06 mm Hg (95% CI, –0.10 to 8.22; P = .056) at the foot, not reaching statistical significance.

Backward stepwise multiple linear regression analysis showed that $TcPo_2$was significantly associated with diabetes (coefficient = –0.258; P = .004) and with having a first-degree relative with diabetes (coefficient = –0.265;

Table II. Mean values for transcutaneous oxygen tension in diabetic patients and nondiabetic patients measured by two different observers

Location	*Patient*	*Observer*	*No.*	*Mean*	*95% CI*	*Difference*	P[a]
Chest	Nondiabetic	Observer 1	60	57.85	54.16-61.54	−0.733	.568
		Observer 2	60	58.58	55.51-61.65		
	Diabetic	Observer 1	60	52.30	48.76-55.84	1.067	.516
		Observer 2	60	51.23	48.31-54.15		
Foot	Nondiabetic	Observer 1	60	55.90	52.76-59.04	−0.283	.875
		Observer 2	60	56.18	53.69-58.67		
	Diabetic	Observer 1	60	49.97	47.64-52.30	−0.117	.925
		Observer 2	60	50.08	47.31-52.85		

CI, confidence interval.
[a]Student's *t* test.

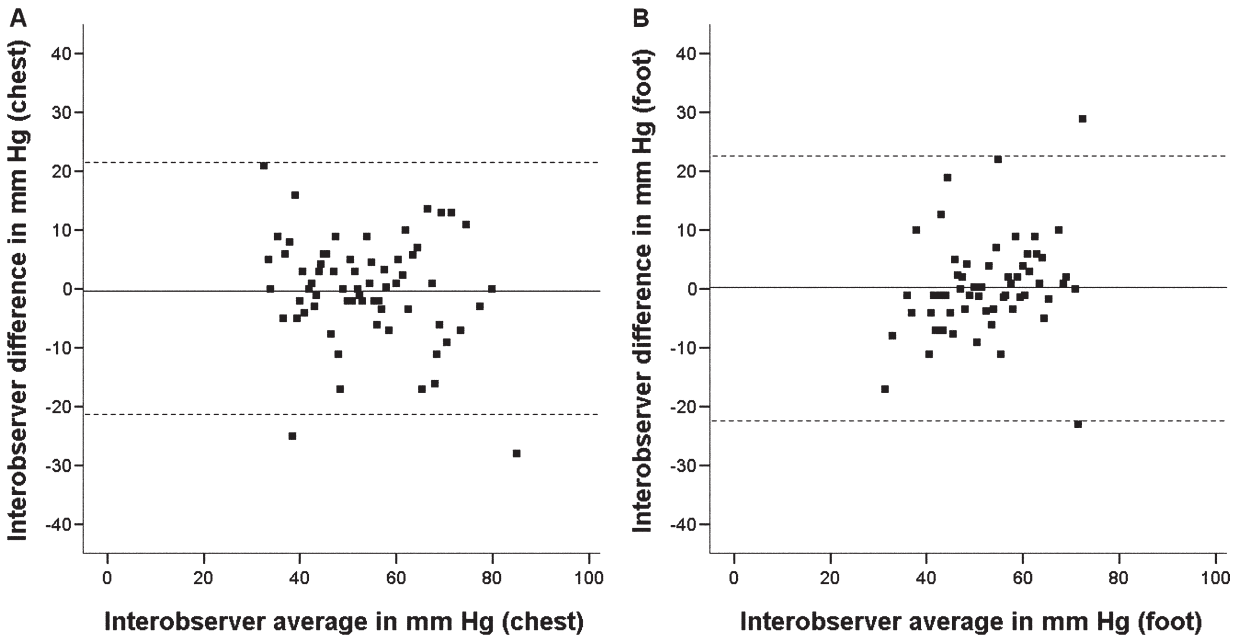

Fig 2. The Bland-Altman distribution shows the difference in transcutaneous oxygen tension ($TcPo_2$) between observer 1 and 2, with the average of $TcPo_2$ in mm Hg for the **(A)** chest and **(B)** foot measurements. The *solid line* shows the mean difference and the *dotted lines* show the 95% confidence interval.

$P = .003$). Cigarette smoking, BMI, type of diabetes, and duration of diabetes showed no significant associations with $TcPo_2$.

Interobserver variability. Table II reports the mean values and corresponding 95% CI for $TcPo_2$ for diabetic and nondiabetic patients as recorded by the different observers. The absolute differences for $TcPo_2$ between observers measured at the chest wall were 1.067 mm Hg (95% CI, –2.20 to 4.33; $P = .516$) for diabetic patients and –0.733 mm Hg (95% CI, –3.29 to 1.83; $P = .568$) for nondiabetic patients. At the dorsum of the foot, the absolute differences for the $TcPo_2$ measurement between observers were –0.117 (95% CI, -2.59 to 2.35; $P = .925$) for diabetic patients and –0.283 (95% CI, –3.86 to 3.29; $P = .875$) for nondiabetic patients (Table II).

The results related to the Bland-Altman analyses show that the distribution of the error was low and, although outliers were present, randomly distributed across the range of values for $TcPo_2$ measured at the dorsum of the foot and chest wall (Fig 2). After a one-way sensitivity analysis by censoring the outlying $TcPo_2$ values >80 mm Hg (7 of 480 individual measurements), the results did not change substantially. Fig 3 presents the correlation of $TcPo_2$ values between observer 1 and 2 for values measured at the chest wall (Fig 3, *A*) and dorsum of the foot (Fig 3, *B*). The values for $TcPo_2$ measured by the different observers at the chest wall and dorsum of the foot were both positively correlated ($r = 0.654$; $P < .001$, and $r = 0.426$; $P < .001$, respectively). The ICC describing the interobserver variation was 0.79 (95% CI, 0.69-0.89; $P < .001$) for all $TcPo_2$ measurements at the chest wall and 0.60 (95% CI, 0.42-0.72; $P < .001$) for all $TcPo_2$ measurements at the dorsum of the foot.

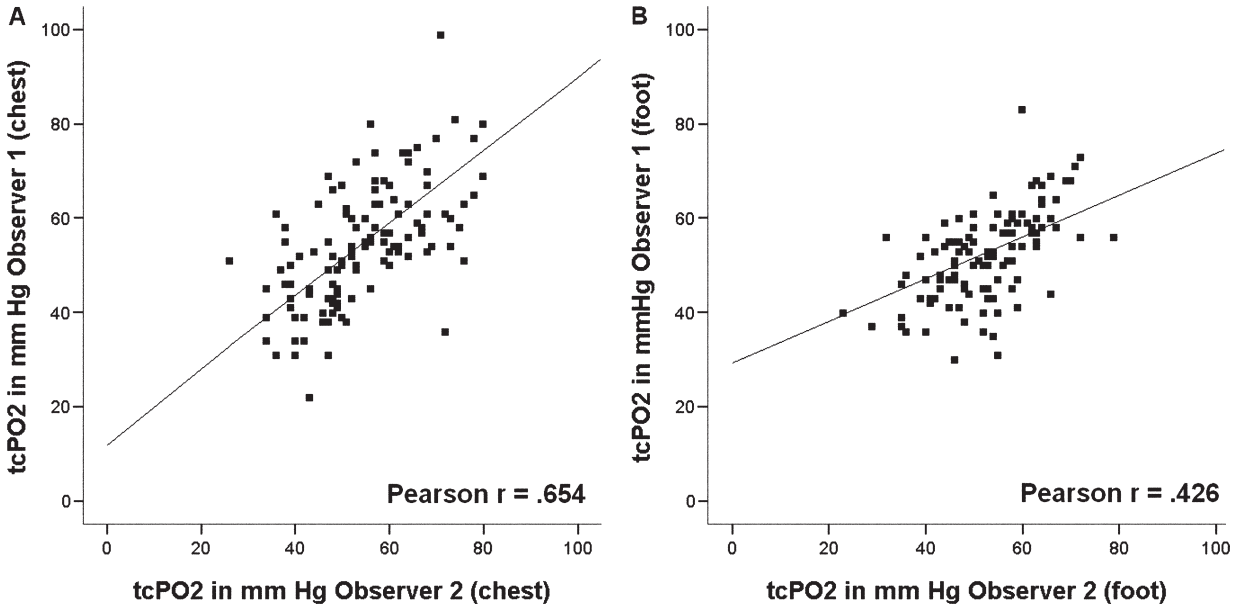

Fig 3. The correlation of transcutaneous oxygen tension ($TcPO_2$) values is shown between observer 1 and 2 for values measured at the **(A)** chest wall and the **(B)** dorsum of the foot.

DISCUSSION

This study assessed mean values for $TcPO_2$ measurements in diabetic patients without signs of peripheral arterial disease compared with age- and sex-matched nondiabetic patients without signs of peripheral arterial disease. The main finding of our study was a significantly lower $TcPO_2$ value measured at both the foot and chest for diabetic patients compared with nondiabetic patients.

Many studies about $TcPO_2$ and diabetes have been published since the 1970s. To our knowledge, however, no studies have been reported in which the study design was to assess a reference value for $TcPO_2$ in diabetic patients. What we do know is that impaired tissue oxygenation is an independent risk factor for diabetic foot ulceration.[25,26] Therefore, consistent reference values for $TcPO_2$ in the diabetic population are crucial to identify patients with a foot at risk. A previous study showed that $TcPO_2$ measurement is also a useful diagnostic modality to prevent peripheral vascular disease in diabetic patients because it detects early changes in skin oxygenation before the development of clinically overt microangiopathy.[27]

In our study we found that when the nondiabetic patients were compared with patients with type 2 diabetes, the values for $TcPO_2$ measured at both the dorsum of the foot and chest wall were significantly lower. However, the absolute differences of $TcPO_2$values at both the dorsum of the foot and chest wall between nondiabetic patients and patients with type 1 diabetes did not reach statistical significance. An explanation could be the difference in number: 25 type 1 diabetic patients were compared with 35 type 2 diabetic patients.

Next, because we found conflicting studies in the literature on the effects of age and sex on $TcPO_2$results,[17,28,29] we matched our patient groups for age and sex. Furthermore, in our study cigarette smoking and BMI showed no association with lower $TcPO_2$ values, which is consistent with the findings by Rooke et al[17] but contrasts with a study by Strauss et al,[30] who identified that cigarette smoking cessation improved the $TcPO_2$value measured at the foot. Despite our results, however, the controversy about the effect of cigarette smoking and BMI on $TcPO_2$ remains.

Further, we also investigated the interobserver variability in $TcPO_2$ measurement. No significant absolute differences were noted between observers. For measurements at foot and chest level, $TcPO_2$ values obtained by both observers simultaneously showed a highly significant correlation. Although variation in the measurements was present, distribution of error was low and randomly assigned across the range of values for $TcPO_2$, meaning that the biologic variance was relatively small. Presented as an ICC value, the interobserver variability showed a substantial correlation for measurements at the chest and at the dorsum of the foot. The ICC value in our study was somewhat smaller compared with the reported ICC value of 0.77 by De Graaff et al,[31] but was identically classified.

The lower ICC value for the $TcPO_2$ measurements obtained at the dorsum of the foot compared with the chest may be explained by the position of the electrodes. Although the electrodes were attached to the first intermetatarsal space as instructed, skin oxygenation could have been influenced by skin thickness and partially positioning the electrode on the metatarsal bony or tendon structures, which may have introduced some variation in our measurements. Overall, the influence of the examiner on the variance in $TcPO_2$measurements appeared to be relatively small.

Several possible limitations of this study warrant consideration. First, by using a cross-sectional design, we are unable to infer causality because the study was done at one time point without follow-up.

Second, because we only provided a snapshot of the situation at one specific point in time, results might be different if another timeframe were chosen. We did not perform repeated measurements, which have previously been shown to introduce greater variability.[31] Our data from the interobserver variability analysis, however, showed a substantial correlation between the measurements taken by both observers at the same time.

Third, because the toe pressure measurements in our first 20 diabetic patients were in the normal range (unpublished data), neither in the subsequently included diabetic patients nor in the nondiabetic patients has the diagnosis of peripheral arterial disease been excluded by additional testing. All patients had bilateral palpable pedal pulses, and all passed standard neurosensory testing. One may rather favor to have baseline values of toe blood pressures or ankle-brachial pressure indexes, or both, to objectively exclude any evidence of peripheral arterial disease; however, these modalities may often lack discriminative accuracy and do not reflect local microvascular perfusion status.

This study was designed in such a way that we relied on the patient's medical history in addition to a comprehensive interview and a routine physical examination to provide a representative sample of patients which physicians daily encounter in clinical practice.

CONCLUSION

Our results demonstrate that diabetic patients without signs of peripheral arterial disease and neuropathy have significantly lower $TcPo_2$ values at both the dorsum of the foot and the chest wall compared with matched nondiabetic patients. The reduced supply of oxygen to the skin in diabetic patients reflects an early subclinical impairment in their microcirculation, thus providing the $TcPo_2$ measurement as an additional tool in the diagnostic armamentarium of vascular surgeons to assess peripheral vascular disease in diabetic patients.

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AUTHOR CONTRIBUTIONS

Conception and design: VM, HS, SS, PH
Analysis and interpretation: VM, SS, PH
Data collection: VM, HS, SS, FK
Writing the article: VM
Critical revision of the article: VM, HS, SS, FK, PH
Final approval of the article: VM, HS, SS, FK, PH
Statistical analysis: VM, SS
Obtained funding: Not applicable
Overall responsibility: PH

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